

Remarks/Arguments

Applicant appreciates the Examiner's indication that Claim 3 was missing from the originally filed claims. A note identifying Claim 3 as missing from the originally filed claims has been added in double brackets, as shown in the **Amendments to and Listing of Claims**.

Applicant also acknowledges with appreciation the Examiner's indication that Claims 7-10 and 13-15 contained allowable subject matter and would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims.

By way of the present amendment, Applicant provides herein amendments to the specification. No new matter has been added by way of these amendments. Applicant has also amended Claims 1, 9-11, 14 and 16; canceled Claims 7, 8, 12 and 13; and added eighteen new claims, Claims 20-37. Thirty-two (32) claims remain pending in the application: Claims 1, 2, 4-6, 9-11 and 14-35 of which Claims 1, 11, 16, 20, 26 and 32 are independent. As noted by the Examiner, Claim 3 was missing from the originally filed claims. Applicant respectfully requests reconsideration of the pending claims, in view of the amendments above and comments below.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected Claims 1, 2, 4, 11 and 16-18 under 35 U.S.C. § 103(a) as being unpatentable over Carter et al. (U.S. Patent No. 6,205,360) in view of Doyle, Sr. (U.S. Patent No. 6,175,767).

The Examiner also rejected Claims 5-7, 12 and 19 under 35 U.S.C. § 103(a) as being unpatentable over Carter et al. (U.S. Patent No. 6,205,360) in view of Doyle, Sr. (U.S. Patent No. 6,175,767), and further in view of Stecker et al. (U.S. Patent No. 6,915,166).

Independent Claim 1 has been amended to include the subject matter from original Claim 7 and the allowable subject matter found in original Claim 8, which claims have been canceled. Independent Claim 11 has been amended to include the subject matter of original Claim 12 and the allowable subject matter found in original Claim 13, which claims have been canceled. Because the allowable subject matter from original Claims 8 and 13 is now found in amended Claims 1 and 11, it is submitted that Claims 1 and 11, and those claims that

depend therefrom, should be patentable for, *inter alia*, at least the same reasons that original claims 8 and 13 were found by the Examiner to contain allowable subject matter.

Regarding the rejection of Claim 16 under 35 U.S.C. § 103(a) as being unpatentable over Carter et al. (U.S. Patent No. 6,205,360) in view of Doyle, Sr. (U.S. Patent No. 6,175,767), Applicant has amended Claim 16 to include similar subject matter found in original Claims 7 and 8. Thus, it is submitted that Claim 16, and those claims that depend therefrom, should be patentable for, *inter alia*, at least the same reasons that original claim 8 was found by the Examiner to contain allowable subject matter.

Double Patenting

The Examiner provisionally rejected Claims 1-6 and 11-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-20 of copending Application Number 10/698,097 (Attorney Docket No. AB-378U). In the event the indicated claims of the referenced copending Application No. 10/698,097 should issue, Applicant has submitted herewith a Terminal Disclaimer which should overcome this provisional rejection.

Newly Added Claims

By way of the present amendment, eighteen (18) new claims have been added. No new matter has been added by way of these amendments.

New independent Claim 20 parallels original independent Claim 1 and further includes the following step:

"delivering the electrical stimuli to selected groups of electrode contacts, such that at least two of the selected groups of electrode contacts output an electrical current into the inner ear tissue, while gradually adjusting the intensity of the electrical stimuli and while monitoring for the occurrence of an evoked compound action potential (ECAP) with another separate electrode contact near the at least two of the selected group of electrode contacts",

which step is not found, taught or suggested by the Carter et al. '360 patent alone or in combination with the Doyle '767 patent.

Carter et al. teach and suggest outputting an electrical stimulus or current with a single electrode to evoke a neural response. The current from the single output electrode completes a circuit with a second indifferent electrode to create a "channel". As explained by Carter et al., "[t]he stimulations are delivered by means of a number of 'channels'. For example, the delivery of a stimulation current *between two* particular electrodes of the array may be defined as a stimulation via channel 1. Similarly other combinations of electrodes involved in stimulation delivery will also define other stimulation channels." (Carter, col. 6, lines 5-10) (emphasis added).

Thus, Carter only describes outputting a stimulus with a single output electrode, paired with an indifferent electrode, to evoke a neural response. Carter does not ever teach or suggest delivering an electrical stimuli where "at least two electrode contacts *output* an electrical current into the inner ear tissue" to evoke an ECAP as claimed. (emphasis added).

As noted above, the teachings of Carter are related to the initial process of determining appropriate stimulation parameters when setting up an implantable ear stimulator. Carter does this by evoking a neural response over a number of "channels," i.e., active and indifferent electrode pairs, to determine initial settings for the stimulator. (See Carter, abstract). While Doyle is also in the field of implantable ear stimulators, Doyle does not address a system or method for determining the appropriate level for stimulation parameters. Doyle is concerned with how the stimulator is operated after it has already been implanted and "fitted" or set-up for the patient.

Consequently, the teachings of Doyle are inapplicable to the teachings of Carter. One of skill in the art would readily appreciate the Doyle and Carter are addressing different things and would never have been lead to combine their teachings.

Consequently, Carter does not teach or suggest the subject matter of independent Claim 20, and one of skill in the art would not be prompted to combine the teachings of Carter and Doyle. Rather, Carter is merely an example of the prior art described and distinguished by the Applicant.

As explained in Applicant's specification, the prior art only teaches using a single electrode to output a stimulus, with a corresponding receiving or indifferent electrode being used to complete a stimulation circuit. The prior art does not teach or suggest two or more electrodes that both "output an electrical current" as an electrical stimuli to produce an occurrence of an evoked compound action potential (ECAP).

As stated in Applicant's specification, "[t]raditional methods used to elicit the electrically-evoked compound action potential, or ECAP, deliver stimulation to a single electrode contact. There are cases where such application of a stimulus to a single electrode contact do not evoke a suitable action potential." See, e.g., page 1, paragraph [0003].

In contrast, Applicant has discovered that by driving two or more electrodes, either simultaneously or in rapid succession, to output an electrical current, an ECAP can be more effectively and reliably evoked. According to Applicant's specification, "electrical stimuli are applied simultaneously (or sequentially at a rapid rate) on selected small groups of electrodes while monitoring the ECAP on a nearby electrode. The presence of an observable ECAP advantageously validates operation of the implant device at a time when the patient may be unconscious or otherwise unable to provide subjective feedback." See, e.g. page 7, paragraph [0024].

From the foregoing, Applicant believes independent Claim 20 should be allowable and its dependent claims, Claims 21-25 should also be allowable.

New independent Claim 26 parallels original independent Claim 11 and further includes the following steps:

- "(c) *simultaneously applying electrical stimuli at the defined stimulation level to the defined group of electrode contacts, wherein at least two of the defined groups of electrode contacts output an electrical current into the inner ear tissue, while gradually adjusting the intensity of the electrical stimuli;*
- (d) *determining whether an evoked compound action potential (ECAP) is observed with another electrode contact near the at least two of the*

defined group of electrode contacts, and if not, adjusting the defined stimulation level and repeating step (c),"

which steps are not found, taught or suggested by the Carter et al. '360 patent alone or in combination with Doyle '767 patent.

For the same reasons stated above, Applicant believes independent Claim 26 should be allowable and its dependent claims, Claims 27-31 should also be allowable.

New independent Claim 32 parallels original independent Claim 16 and further includes the following limitation:

"means for delivering the electrical stimuli to selected groups of electrode contacts, such that at least two of the selected groups of electrode contacts output an electrical current into the inner ear tissue, while gradually adjusting the intensity of the electrical stimuli and while monitoring for the occurrence of an evoked compound action potential (ECAP) with another separate electrode contact near the at least two of the selected groups of electrode contacts receiving the delivered electrical stimuli for the occurrence of an evoked compound action potential (ECAP)",

which limitation is not found, taught or suggested by the Carter et al. '360 patent alone or in combination with Doyle '767 patent. Similarly, for the reasons stated above, Applicant believes independent Claim 32 should be allowable and its dependent claims, Claims 33-37 should also be allowable.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections have been overcome and that the pending claims are in condition for allowance. An indication of allowability of Claims 1, 2, 4-6, 9-11 and 14-37 at an early date is thus earnestly solicited.

The Examiner is invited to telephone the undersigned, Victoria A. Poissant, should any issues remain after consideration and entry of this response, in order to permit early resolution of such issues.

Respectfully Submitted,

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